

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/480,389 01/11/00 BOMAN

B CATX-N

024988
LEONA L LAUDER
369 PINE STREET
SUITE 610
SAN FRANCISCO CA 94104-3313

HM12/0330

EXAMINER

DAVIS, M

ART UNIT

PAPER NUMBER

1642
DATE MAILED:

10.
03/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 399
09/480,398

Applicant(s)

Boman et al

Examiner

Minh-Tam Davis

Group Art Unit

1642



☒ Responsive to communication(s) filed on Dec 19, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-48 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-48 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-48, drawn to a method for detecting a disease comprising determining whether no wild-type protein expressed by a subject gene is present in a sample, due to mutation in each of the alleles of said subject gene, classified in class 435, subclass 7.1.

Group II. Claims 1-48, drawn to a method for detecting a disease comprising determining whether there is an abnormal low level of wild-type protein expressed by a subject gene in a sample, due to mutation in one of the alleles of said subject gene, classified in class 435, subclass 7.1.

In addition, upon the election of any of groups I-II, further election of the following patentably distinct species of the claimed invention is required:

- 1) Germline mutations or somatic mutations.
- 2) Any one of the biological samples recited in claim 9.
- 3) Any one of the detection methods recited in claim 22.
- 4) Any one of the genes recited in claims 16, 38 and 41.
- 5) Any one of the disease recited in claim 17 and 39.

Upon election of the species body fluids, further election of the following patentably distinct species of the claimed invention is required:

Art Unit: 1642

Any one of the body fluid recited in claim 10.

2. The inventions are distinct, each from the other because of the following reasons:

The method of groups I is distinct from the method of groups II, because losing one allele of a gene could result in different diseases and/or disease conditions and disease susceptibility, as compared to losing both alleles of a gene, in which the protein encoded by said gene is completely lost, and because the methods differ at least in method steps, based on different expression properties of a gene.

Further, different types of mutations are patentably distinct because different type of mutation could result in different diseases and/or disease conditions and disease susceptibility.

Different genes are patentably distinct because they are structurally distinct.

The species germline mutations and somatic mutations are distinct because they involve different sites of mutation.

The species biological samples and body fluids are distinct because they are different biochemicals with different properties.

The species methods of detection are patentably distinct because they use different method steps, reagents and/or dosages.

Different diseases are patentably distinct because they are

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Art Unit: 1642

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

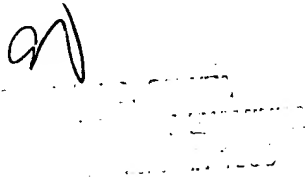
Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

March 22, 2001

A handwritten signature, possibly "an", is written over a faint rectangular stamp. The stamp contains some illegible text, possibly a date or a reference number.